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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | | |
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| 09/923,122 | 08/06/2001 | Gilberto Bestetti | 6330.01 | 9725 | | |
| 7590 | 08/30/2005 | | | | | |
| EXAMINER | | | | HAYES, MICHAEL J | | |
| DAVID E. BRUHN DORSEY & WHITNEY LLP INTELLECTUAL PROPERTY DEPARTMENT SUITE 1500, 50 SOUTH SIXTH STREET MINNEAPOLIS, MN 55402-1498 | | ART UNIT | | PAPER NUMBER | | |
| | | | | 3763 | | |
| DATE MAILED: 08/30/2005 | | | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/923,122 | BESTETTI ET AL. | |
| | Examiner | Art Unit | |
| | Michael J. Hayes | 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 13 June 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 20-28 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 20-28 and 30-35 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 06 August 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-24 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 20-24 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted elements are: those elements that provide an area on which skin cannot grow. Applicant has not recited elements and/or structural relationships between elements that cause this function limitation to occur.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by ANDREUSSI (US Patent No. 5,064,417). Andreussi discloses an implantable device having a shaft, upper fin, lower fin and a pocket with a gap between the edges of the fins that is less than a diameter of a cross-sectional diameter of the pocket. Fig. 2 shows the edges of fins 4, 2 to be closer than a diameter (i.e., a line through the center of a shape) of a cross-section of the pocket.

Claims 25, 31, 32, 33, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by BENTLEY et al. (US Patent No. 4183357). Bentley discloses an implantable device having a shaft, radial and anchoring fins forming a rounded cross-sectional pocket 51. The device has an upper and lower fins and an anchoring plate extending from the lower fin. See fig. 5.

Claim 25 is rejected under 35 U.S.C. 102(b) as being anticipated by HARGEST (US Patent No. 3,461,869). Hargest discloses an implantable device having a shaft, radial and anchoring fins with a rounded cross-sectional pocket 24 between them. See figs. 3,7.

Claims 25 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by GIFFORD, III et al. (US Patent No. 5,817,113). Gifford discloses a device having a shaft, radial fin 168, 637 anchoring fin 167, 636 and a rounded pocket formed by the fins that has a distance between the edges of the fins less than the diameter of the rounded cross-section of the pocket. See figs. 9, 10, 12, 48B.

Claims 25, 31, 32, 33, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by BOKROS (US Patent No. 3783868). Bokros discloses an implantable device having a shaft, upper and lower fins, and an anchoring plate attached to the lower, central and peripheral portions disposed along first and second radial planes further than the first. See fig. 2.

Claims 25, 31-33, and 35 are rejected under 35 U.S.C. 102(b) as being anticipated by SLIVENKO (US Patent No. 4,108,173). Silvenko discloses an implantable device having a shaft, upper and lower fins, and an anchoring plate attached to the lower, central and peripheral portions disposed along first and second radial planes further than the first. See fig. 7.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over BENTLEY as applied to claim 25 above, and further in view of BOKROS (US Patent No. 3783868). Bentley discloses the claimed invention except for a disc-shaped anchoring plate around the shaft with an anchoring fin. Bokros teaches a disc-shaped anchoring plate 26 around a shaft with an anchoring fin 52 protruding therefrom. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Bokros in the invention of Bentley in order to provide anchoring structure to prevent unwanted movement of the implantable device.

Claims 21, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over ANDREUSSI as applied to claims 20 and 23 above, and further in view of SLIVENKO (US Patent No. 4,108,173). Andreussi discloses the claimed invention except for an anchoring plate extending from the lower fin that extends away from the skin. Slivenko discloses an anchoring

plate 87 attached to the lower fin that extends away from the skin. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Slivenko in the device of Andreussi to obtain a greater level of stability for the implantable device to prevent the device from becoming dislodged.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over BENTLEY or HARGEST as applied to claim 25 above and further in view of BROEMER (US Patent No. 4,365,356). Bentley and Hargest disclose the claimed invention except for a bio-active material partially coated on the device. Broemer teaches application of a bio-active material on an implantable device to facilitate tissue ingrowth with the device, 2:1-11.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over BENTLEY, SLIVENKO, or BOKROS as applied to claim 31 above and further in view of BROEMER (US Patent No. 4,365,356). Bentley, Slivenko, and Bokros each disclose the claimed invention except for a bio-active material partially coated on the anchoring plate. Broemer teaches application of a bio-active material on an implantable device to facilitate tissue ingrowth with the device to facilitate anchoring (2:1-11).

Response to Arguments

Applicant argues that the prior art does not disclose an area on which skin cannot grow. The examiner disagrees and maintains the rejections because the prior art discloses all claimed structure recited in the claims. Applicant has not identified any structure to perform this negative limitation. Applicant has not pointed to any disclosure in the prior art that states skin can grow on an area of the device. Growing on an area of the device is distinguished from skin covering the device. Applicant's device and the prior art are capable of having skin cover the device. The

prior art discloses the claimed structure and is capable of performing the functions recited in the claims. The prior art is capable of having skin growth or no skin growth in view of the disclosed structures as recited in Applicant's claims.

Applicant's remark that a washer disclosed in '417 permits skin growth is unsubstantiated with statements from the prior art.

Applicant argues that Hargest does not disclose a generally cylindrical hollow shaft. The examiner disagrees and refers Applicant to figs. 2, 5, 6, and 7 of the prior art where a generally cylindrical hollow shaft housing is shown.

Applicant argues that the cross section disclosed by Gifford is not rounded. The examiner disagrees and points to figs. 10 and 12 where a rounded cross section is shown when the fin 168 is in its distal position.

Applicant argues that the prior art does not disclose tissue ingrowth. The examiner maintains the rejection because the prior art is capable of providing tissue ingrowth due to its shape and surface. The structural limitations recited in the claims read on the prior art and if Applicant's structure is capable of performing the function than the prior art is also.

Applicant argues that Andreussi has no upper fin. The examiner disagrees and points to 4, fig. 2.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday - Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (571) 272-4977. The fax number for submitting official papers is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
25 August 2005



MICHAEL J. HAYES
PRIMARY EXAMINER